



PATENT

Our Docket: 67493-013 (P-PM.4966)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|-------------------------------|---|-----------------------|
| In re Application of |) | Group Art Unit: 1648 |
| Braun and Sutton |) | |
| Serial No: 09/966,608 |) | Examiner: L. Scheiner |
| Filed: September 27, 2001 |) | |
| For: IBD-ASSOCIATED MICROBIAL |) | |
| NUCLEIC ACID MOLECULES |) | |

Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.131

We, Jonathan Braun and Christopher L. Sutton, hereby
declare as follows:

1. We, Jonathan Braun and Christopher L. Sutton, are
co-inventors of the above-identified patent application.

2. We understand that several claims of the
above-identified patent application stand rejected, in part, over
Rubenfield et al. (U.S. Patent No. 6,551,795), which claims
priority to provisional applications filed on February 18, 1998,
and July 27, 1998. Attached hereto as Exhibit A is the front
page of U.S. Patent No. 6,551,795, showing the filing dates of
the two priority applications.

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 2

3. Attached as Exhibit B is a copy of Figure 1 of the above-identified application. Figure 1 shows the I-2 nucleotide sequence SEQ ID NO:1 and predicted I-2 amino acid sequence SEQ ID NO:2.

4. This Declaration attests that we obtained the I-2 nucleotide sequence SEQ ID NO:1 and the predicted I-2 amino acid sequence SEQ ID NO:2 prior to February 18, 1998, which is the earliest priority date of Rubenfield et al. (U.S. Patent No. 6,551,795). Documentary evidence in support thereof is attached as Exhibits C, D and E.

5. Prior to February 18, 1998, we conducted research directed to obtaining and sequencing the claimed I-2 nucleic acid molecule. Identifying and sequencing of the I-2 clone arose out of collaborative discussions regarding sequences differentially expressed in inflamed Crohn's disease lesions as compared to uninfamed tissue. The actual experiments resulting in isolating and sequencing I-2 nucleic acid molecule SEQ ID NO: 1 were performed by Dr. Sutton or under his supervision.

6. As evidence that the I-2 nucleic acid molecule SEQ ID NO:1 was obtained and sequenced prior to February 18, 1998, attached as Exhibit C is a copy of an electropherograph documenting the sequence analysis of the I-2 clone. The electropherograph has been marked with arrows to indicate the first and last nucleotides corresponding to I-2. Although the dates of sample processing and data output printed on the electropherograph have been redacted, these dates are prior to February 18, 1998. Furthermore, a comparison of

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 3

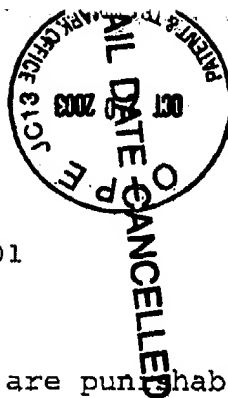
SEQ ID NO:1 with the relevant portion of the electropherograph nucleotide sequence, attached as Exhibit D, indicates that complete SEQ ID NO:1 is included on the electropherograph. These results indicate that the complete I-2 nucleotide sequence SEQ ID NO:1 had been obtained prior to February 18, 1998.

7. As evidence that the predicted I-2 amino acid sequence SEQ ID NO:2 had been determined by us prior to February 18, 1998, attached as Exhibit E is a copy of a DNA STRIDER output. The DNA STRIDER output shows that a 6-phase open reading frame map was prepared for the 302 base pair I-2 nucleotide sequence shown in the electropherograph in Exhibit C. To corroborate that the DNA STRIDER output corresponds to the I-2 sequence shown in the electropherograph, the 12-base pair segments at the 5' and 3' ends of the DNA STRIDER query sequence, shown as "AGATCTGGCCAG...ATGAGCAGATCT" on the DNA STRIDER output, are highlighted in the I-2 nucleotide sequence in Exhibit C. The DNA STRIDER output is dated prior to February 18, 1998, with the actual date having been redacted.

8. The results described in paragraphs 6 and 7 demonstrate that the nucleotide sequence of I-2 nucleic acid molecule SEQ ID NO:1 and corresponding encoded amino acid sequence SEQ ID NO:2 were known to us prior to February 18, 1998.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 4



statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date: 10/17/03

By: Jonathan Braun
Jonathan Braun

Date: _____

By: _____
Christopher L. Sutton

Inventors: Braun and Sutton
Serial No.: 09/966,608
Filed: September 27, 2001
Page 4

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Date: _____

By: _____

Jonathan Braun

Date: 10/20/03

By: CS L Sutton

Christopher L. Sutton